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10/576,240

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Iris Meiri-Bendek

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EXAMINER

WATTS, JENNA A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,240	Applicant(s) MEIRI-BENDEK ET AL.	
	Examiner Jenna A. Watts	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 6, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 5, 6, 16 and 17 recite the limitation "said unsaturated fatty acids" in line 2 of Claims 5 and 6 and line 1 of Claims 16 and 17. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-10, 13-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (U.S. Patent No. 4,876,107) in view of Innis et al. (American Institute of Nutrition, 1995), both previously made of record.

8. Regarding Claims 1-3 and 9, King teaches an enzymatically prepared fat base composition comprising a mixture of vegetable derived triglycerides because King teaches a substitute milk fat composition for use in feeding young mammals and especially infants (Column 1, lines 7-8), thus deemed a substitute human milk fat composition and an infant formula, and teaches various embodiments of the fat base composition (see Blends 1-4, Table 3) wherein the total palmitic acid residues content is at most 38% of the total fatty acid residues because King teaches embodiments wherein the palmitic acid residues are between 26-33% of the total fatty acid

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composition of the blends (see Table 3, % of 16:0 in Blends 1-4). King further teaches that at least half of the fatty acid residues in the sn2-position are C16 and/or C18 saturated, preferably consisting substantially of palmitic acid, particularly 60-90% by weight of the total 2-position fatty acids (Column 2, lines 25-29). King teaches that such an arrangement results from the rearrangement of vegetable fat via enzymes (Column 3, lines 20-25). King further teaches that milk replacement fats should match the performance of milk fat as closely as possible in order to reproduce its physical and dietary characteristics and teaches that human milk fat consists of a variety of triglycerides of both saturated and unsaturated fatty acids (Column 1, lines 13-18). King further teaches that the proportions of infant formulations have been adjusted from time to time in an effort to develop a formula more nearly approximating to mother's milk (Column 1, lines 25-27).

9. However, King does not specifically teach embodiments of the enzymatically prepared fat base composition where both the total palmitic acid residues are at most 38% of the total fatty acid residues and at least 60% of the fatty acid residues at the sn-2 position of the glycerol backbone are palmitic acid residues.

10. Innis teaches that palmitic acid represents 20-30% of the fatty acids in human and pig milk, and around 70% of this is esterified to the sn-2 position of the milk triacylglycerol (Column 1, lines 1-5).

11. Therefore, Innis teaches the composition of human milk and King teaches that it is known and beneficial to develop infant formulas that approximate the fatty acid profile of mother's milk in order to reproduce its physical and dietary characteristics, and King

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further teaches various embodiments of the fat base composition that possess the fatty acid profile taught by Innis, which meets the palmitic acid profile of Claim 1.

12. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the enzymatically prepared fat base composition of King to have the claimed composition of fatty acids, because King teaches embodiments that possess the claimed amount of total palmitic acid residues and the amount of palmitic acid present at the sn-2 position of the glycerol backbone, and teaches the importance of developing infant formulas that possess a fatty acid profile that approximates mother's milk and Innis teaches the specific fatty acid profile of human milk from the perspective of the amount of palmitic acid residues. Therefore, one of ordinary skill in the art would have been motivated by both King and Innis to develop a fat base composition for use in infant formulas that approximates, as close as possible, the palmitic acid profile of human milk in order to provide a suitable substitute to human milk for infants.

13. Regarding Claim 4-6, King in view of Innis teach that sn-1 and sn-3 positions include unsaturated fatty acids, preferably largely consisting of oleic and linoleic acids (see King, Column 2, lines 30-33) and further teach embodiments of the fat base composition wherein at least 70% of the fatty acid residues at the sn-1 and sn-3 positions are oleic and other unsaturated fatty acid residues because King in view of Innis teach that the combination of oleic and linoleic fatty acids are 75% and 65% at the sn-1 and sn-3 positions respectively for embodiments 3 and 4 of the fat base composition. King in view of Innis further teach that at least 40% of the unsaturated fatty

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acids at the sn-1 and sn-3 positions are oleic acid residues because King in view of Innis teach embodiments wherein oleic acid (18:1) ranges from 39-61% at the sn-1 and sn-3 positions (see King, Table 3, % of 18:1). King in view of Innis further teach that at least 6% of the fatty acid residues at the sn-1 and sn-3 position are linoleic acid residues because King in view of Innis teach embodiments wherein linoleic acid (18:2) ranges from 11-21.5% at the sn-1 and sn-3 positions (see King, Table 3, % of 18:2). King in view of Innis further teach that the proportion and variety of the fatty acids may be determined in accordance with dietary and physical requirements of the composition required (see King, Column 2, lines 39-41).

14. Regarding Claims 7 and 8, King in view of Innes further teach that other fats may be included in the composition of the invention, including vegetable oils, for example sunflower oil and soya bean oil, having a high content of polyunsaturated fatty acid glycerides, to improve the dietary benefit of the compositions of the invention (see King, Column 2, lines 50-53). King in view of Innis further teach that the substitute milk fat composition comprises 10-30% vegetable oil, which is below 75%, and the balance of the substitute milk fat composition would be the enzymatically rearranged vegetable fat composition (see King, Column 6, Claims 6 and 8). Therefore, the enzymatically rearranged vegetable fat composition would be present at at least 25% of the substitute milk fat composition. King in view of Innis further teach that the resulting infant formula provides fat, protein and carbohydrate, where in the fat normally found in such formulations is replaced by an enzymatically rearranged fat in accordance with the present invention (see King, Column 3, lines 20-25).

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15. Regarding Claim 10, since vitamins, minerals, nucleotides, amino acids and carbohydrates are optional elements, King in view of Innis meet the claimed limitations.

16. Regarding Claim 13, King in view of Innis are taken as cited above in the rejection of Claim 7 and are deemed to teach a process of preparing the substitute human milk fat composition comprising admixing vegetable oil with the fat base composition (see rejection of Claim 7).

17. Regarding Claims 14 and 15, King in view of Innis are taken as cited above in the rejection of Claims 1 and 7 and are deemed to teach the fat base composition for use in the preparation of a substitute human milk fat composition for infant formula and for use in the preparation of an infant formula. (see rejection of Claims 1 and 7-10).

18. Regarding Claims 16 and 17, King in view of Innis are taken as cited above in the rejection of Claims 5 and 6 above.

19. Regarding Claim 19, King in view of Innis are taken as cited above in the rejection of Claim 7 and further teach that vegetable oils, for example sunflower oil and soya bean oil, having a high content of polyunsaturated fatty acid glycerides, can be added to the composition to improve the dietary benefit of the compositions of the invention (see King, Column 2, lines 50-53). King in view of Innis do not specifically teach that the substitute human milk fat composition comprises blending with 50 to 75% of at least one vegetable oil.

20. However, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, to optimize the amount of vegetable oil in the substitute human milk fat composition in order to provide a substitute milk fat composition that

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comprises an ideal amount of polyunsaturated fatty acid glycerides, which are known to improve the dietary benefit of the composition. One of ordinary skill in the art would have been motivated by cost and the nutritional requirements of the resulting substitute milk fat composition to optimize the amount of vegetable oil present in order to provide consumers with a cost effective and nutritionally viable alternative to human milk.

21. Furthermore, the amount of vegetable oil added to the composition does not appear to be critical in light of Claim 7, wherein the vegetable oil can be present in amounts up to 75% of the composition.

22. Claims 11, 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (U.S. Patent No. 4,876,107) in view of Innis et al. (American Institute of Nutrition, 1995), and further in view of Cooper (U.S. Patent No. 5,371,253), all previously made of record.

23. Regarding Claims 11, 12 and 18, King in view of Innis are relied upon as cited above in the rejection of Claim 1.

24. Regarding Claims 11 and 18, King in view of Innis are taken as cited above in the rejection of Claim 1 and teach a process of preparing an enzymatically rearranged fat composition comprising the steps of: (a) reacting an upper-melting fraction of palm oil, which is expected to be rich in palmitic acid, with oleic acid, in the presence of lipase deposited on Celite (see King, Column 4, lines 51-55), which is deemed an insoluble catalyst in view of Applicant's disclosure and use of an immobilized lipase per Example 1 on Page 16 of Applicant's specification. It is noted that King also uses hexane in the

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process, but since Claim 11 claims "comprising the steps of", this does not preclude the use of other elements also present in the process. King in view of Innis further teach (b) removing the catalyst, and (c) distilling the free fatty acids (see King, Column 4, lines 62-68). Since step (e) is optional, King in view of Innis are deemed to meet the claim limitation.

25. Regarding Claims 11 and 12, King in view of Innis do not specifically teach the step (d) of bleaching the oil after distilling and also do not specifically teach the step of fractionation preceding deodorization.

26. Cooper teaches that processing steps such as degumming, bleaching, filtration, deodorization, fractional crystallization, which is deemed to meet the limitation of a fractionation step, and the like are techniques known in the art for refining natural vegetable or animal oils and fats and that products produced from fatty acids, such as palm oil or palm kernel oil, can be additionally purified or treated using such techniques (Column 8, lines 64-68, Column 9, lines 1-3 and Column 10, lines 46-47 and 64-66).

27. Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made, for the process of preparing a fat base composition to have further comprised the step of bleaching and a step of fractionation preceding deodorization, because Cooper teaches that bleaching, deodorization and fractionation are techniques known in the art for refining natural vegetable or animal oils and teaches such techniques can be used on products produced from palm oil or palm kernel oil. One of ordinary skill in the art would have been motivated by Cooper to use such known

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techniques as bleaching, deodorizing and fractionation for their known benefits in order to produce a more refined or treated final product.

28. Regarding the specific series of method steps in Claim 12, it has been found that “selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results.” See MPEP 2144.04 IV C. In the instant case, the selection of the order of the deodorization and fractionation steps after the step of bleaching would be expected to be obvious to one of ordinary skill in the art at the time that the invention was made, in order to efficiently and economically prepare a fat base composition of the desired purity and quality.

Response to Arguments

29. The claim objections, 35 U.S.C. 112 2nd rejections and 35 U.S.C. 101 rejections set forth in the office action mailed on 6/18/2009 have been withdrawn in light of Applicant’s amendments.

30. The 35 U.S.C. 102 and 103 rejections set forth in the office action mailed on 6/18/2009 have been withdrawn in light of Applicant’s amendments.

31. Applicant’s arguments, filed 10/19/2009 with respect to the rejection(s) of the pending claim(s) under 35 U.S.C. 102 and 103 have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over King in view of Innis for the reasons set forth above. Additionally, a new rejection under 35 U.S.C. 112 2nd

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Paragraph of Claims 5, 6, 16 and 17 have been set forth for the reasons set forth above.

32. Regarding Applicant's arguments on Page 11 of 16 of the amount of fat base used in the blends of King, since King teaches an embodiment of the substitute milk fat composition wherein the fat base composition can be present in an amount from about 50-70% of the composition, the vegetable oil from 10-30% and lauric fat in an amount of 20% (see Claims 7 and 8 of King), and Applicant's Claim 7 requires the fat base composition to be present in an amount of at least 25% and from at least 25 to 50% of the composition in the case of Claim 19, King meets the claimed limitations for the amount of fat base present.

33. Furthermore, regarding Applicant's argument relating to the use of hexane in the process of King, it is noted that, firstly, the claims as currently presented do not claim a method free of hexane, and secondly, as stated in the previously mailed office action as well as above, since Claim 11 uses "comprising" language, such a method does not preclude the use of other components, including for example, the use of hexane in the method. Therefore, in this light, King meets the claimed limitations for steps a-c of the method of Claim 11.

Conclusion

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNA A. WATTS whose telephone number is (571) 270-7368. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

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35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1794

/Jenna A. Watts/
Examiner, Art Unit 1794
February 17, 2010